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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs, v. AMNEAL PHARMACEUTICALS LLC, Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB (collectively "Plaintiffs" or "AstraZeneca") bring this action for patent infringement against Amneal Pharmaceuticals LLC ("Defendant" or "Amneal").

THE PARTIES

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850, U.S.A.

2. Plaintiff AstraZeneca UK Limited is a private limited company organized under

the laws of England and Wales, with its registered office at 2 Kingdom St, London W2 6BD, United Kingdom.

3. Plaintiff AstraZeneca AB is a public limited liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

4. On information and belief, Defendant Amneal Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807-2863.

5. On information and belief, Defendant is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this District.

NATURE OF THE ACTION

6. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendant's ANDA No. 210044, filed with the FDA seeking approval to engage in the commercial manufacture, use and sale of Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) prefilled syringes (the "Proposed ANDA Product"), which is a generic version of AstraZeneca's FASLODEX® (fulvestrant) intramuscular injection product, prior to the expiration of AstraZeneca's U.S. Patent Nos. 6,774,122, 7,456,160, 8,329,680, and 8,466,139.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and

2202.

8. This Court has personal jurisdiction over Amneal because of its continuous and systematic contacts with this State. On information and belief, Amneal: (1) maintains its principal place of business in this State; (2) is registered to do business in this State; (3) intentionally markets and provides its generic pharmaceutical products to residents of this State; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales in this State. Moreover, Amneal has previously submitted to personal jurisdiction in this judicial district.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

THE PATENTS-IN-SUIT

10. United States Patent No. 6,774,122 (the "'122 Patent"), entitled "Formulation," was duly and legally issued on August 10, 2004 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '122 Patent. AstraZeneca UK Limited is the beneficial owner of the '122 Patent. A copy of the '122 Patent is attached as Appendix A.

11. United States Patent No. 7,456,160 (the "'160 Patent"), entitled "Formulation," was duly and legally issued on November 25, 2008 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '160 Patent. AstraZeneca UK Limited is the beneficial owner of the '160 Patent. A copy of the '160 Patent is attached as Appendix B.

12. United States Patent No. 8,329,680 (the "'680 Patent"), entitled "Formulation," was duly and legally issued on December 11, 2012 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is

the legal owner of the ’680 Patent. AstraZeneca UK Limited is the beneficial owner of the ’680 Patent. A copy of the ’680 Patent is attached as Appendix C.

13. United States Patent No. 8,466,139 (the “’139 Patent”), entitled “Formulation,” was duly and legally issued on June 18, 2013 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the ’139 Patent. AstraZeneca UK Limited is the beneficial owner of the ’139 Patent. A copy of the ’139 Patent is attached as Appendix D.

FACTUAL BACKGROUND

FASLODEX® (fulvestrant) intramuscular injection

14. FASLODEX® (fulvestrant) intramuscular injection is an estrogen receptor antagonist approved by the FDA for the treatment of hormone receptor (HR)-positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy. FASLODEX® (fulvestrant) intramuscular injection is also approved by the FDA for the treatment of HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression after endocrine therapy, which is subject to new indication exclusivity until February 19, 2019.

15. AstraZeneca UK Limited is the holder of approved New Drug Application (“NDA”) No. 21-344 for FASLODEX® (fulvestrant) intramuscular injection, in 50 mg/mL dosage forms. AstraZeneca Pharmaceuticals LP is the authorized agent for matters related to NDA No. 21-344 in the United States.

16. The use of FASLODEX® (fulvestrant) intramuscular injection is covered by one or more Claims of the ’122, ’160, ’680, and ’139 Patents, and the ’122, ’160, ’680, and ’139 Patents have been listed for NDA No. 21-344 in the FDA’s publication, *Approved Drug*

Products with Therapeutic Equivalence Evaluations, which is referred to as the "Orange Book."

17. AstraZeneca Pharmaceuticals LP sells and distributes FASLODEX® (fulvestrant) intramuscular injection in the United States pursuant to NDA No. 21-344.

DEFENDANT'S ANDA

18. By letter dated March 7, 2017 (the "Notice Letter"), Defendant Amneal notified AstraZeneca that Defendant's ANDA No. 210044, submitted to the FDA by Amneal, sought approval to engage in the commercial manufacture, use and sale of the Proposed ANDA Product prior to the expiration of the '122, '160, '680, and '139 Patents, and included within ANDA No. 210044 a certification pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '122, '160, '680, and '139 Patents are invalid and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product.

19. On information and belief, Defendant was necessarily aware of the Patents-in-Suit when ANDA No. 210044 was filed with a Paragraph IV Certification.

20. On information and belief, ANDA No. 210044 refers to and relies upon the FASLODEX® (fulvestrant) intramuscular injection NDA and contains data that, according to Defendant, demonstrate the bioequivalence of the Proposed ANDA Product and FASLODEX® (fulvestrant) intramuscular injection.

21. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions for FASLODEX® (fulvestrant) intramuscular injection, including instructions for administering the Proposed ANDA Product by intramuscular injection to treat hormone receptor (HR)-positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy. The

instructions accompanying the Proposed ANDA Product will induce others to use and/or contribute to others' use of the Proposed ANDA Product in the manner set forth in the instructions. Defendant Amneal is blocked from seeking approval from the FDA to engage in the commercial manufacture, use and sale of the Proposed ANDA Product to treat HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression after endocrine therapy prior to the expiration of AstraZeneca's data exclusivity on February 19, 2019.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,774,122

22. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 21 of this Complaint.

23. The use of the Proposed ANDA Product is covered by one or more Claims of the '122 Patent.

24. Defendant's submission of ANDA No. 210044 under 21 U.S.C. § 505(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '122 Patent constitutes infringement of one or more Claims of the '122 Patent under 35 U.S.C. § 271(e)(2).

25. On information and belief, Defendant plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 210044 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

26. On information and belief, the Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '122 Patent under 35 U.S.C. § 271(a).

27. Upon FDA approval of ANDA No. 210044, Defendant will infringe the '122 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

28. On information and belief, Defendant had knowledge of the '122 Patent when it submitted ANDA No. 210044 to the FDA and Defendant knows or should know that it will aid and abet another's direct infringement of at least one of the Claims of the '122 Patent.

29. The Notice Letter lacks any legal or factual basis for non-infringement of any Claims of the '122 Patent.

30. Defendant has knowledge of the '122 Patent and is knowingly and willfully infringing the '122 Patent.

31. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

32. On information and belief, Defendant lacked a good faith basis for alleging invalidity of the '122 Patent when it filed its Paragraph IV Certification. Accordingly, Defendant's Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,774,122

33. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 32 of this Complaint.

34. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and

2202.

35. On information and belief, Defendant has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of the '122 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 210044 is approved.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,456,160

36. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 35 of this Complaint.

37. The use of the Proposed ANDA Product is covered by one or more Claims of the '160 Patent.

38. Defendant's submission of ANDA No. 210044 under 21 U.S.C. § 505(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '160 Patent constitutes infringement of one or more Claims of the '160 Patent under 35 U.S.C. § 271(e)(2).

39. On information and belief, Defendant plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 210044 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

40. On information and belief, the Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '160 Patent under 35 U.S.C. § 271(a).

41. Upon FDA approval of ANDA No. 210044, Defendant will infringe the '160 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others

under 35 U.S.C. § 271(b) and/or (c).

42. On information and belief, Defendant had knowledge of the '160 Patent when it submitted ANDA No. 210044 to the FDA and Defendant knows or should know that it will aid and abet another's direct infringement of at least one of the Claims of the '160 Patent.

43. The Notice Letter lacks any legal or factual basis for non-infringement of any Claims of the '160 Patent.

44. Defendant has knowledge of the '160 Patent and is knowingly and willfully infringing the '160 Patent.

45. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

46. On information and belief, Defendant lacked a good faith basis for alleging invalidity of the '160 Patent when it filed its Paragraph IV Certification. Accordingly, Defendant's Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,456,160

47. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 46 of this Complaint.

48. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

49. On information and belief, Defendant has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of the '160 Patent under 35 U.S.C.

§ 271(b) and/or § 271(c), after ANDA No. 210044 is approved.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 8,329,680

50. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 49 of this Complaint.

51. The use of the Proposed ANDA Product is covered by one or more Claims of the '680 Patent.

52. Defendant's submission of ANDA No. 210044 under 21 U.S.C. § 505(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '680 Patent constitutes infringement of one or more Claims of the '680 Patent under 35 U.S.C. § 271(e)(2).

53. On information and belief, Defendant plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 210044 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

54. On information and belief, the Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '680 Patent under 35 U.S.C. § 271(a).

55. Upon FDA approval of ANDA No. 210044, Defendant will infringe the '680 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

56. On information and belief, Defendant had knowledge of the '680 Patent when it submitted ANDA No. 210044 to the FDA and Defendant knows or should know that it will

aid and abet another's direct infringement of at least one of the Claims of the '680 Patent.

57. The Notice Letter lacks any legal or factual basis for non-infringement of any Claims of the '680 Patent.

58. Defendant has knowledge of the '680 Patent and is knowingly and willfully infringing the '680 Patent.

59. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

60. On information and belief, Defendant lacked a good faith basis for alleging invalidity of the '680 Patent when it filed its Paragraph IV Certification. Accordingly, Defendant's Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,329,680

61. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 60 of this Complaint.

62. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

63. On information and belief, Defendant has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of the '680 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 210044 is approved.

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 8,466,139

64. Plaintiffs hereby reallege and incorporate by reference the allegations of

paragraphs 1 – 63 of this Complaint.

65. The use of the Proposed ANDA Product is covered by one or more Claims of the '139 Patent.

66. Defendant's submission of ANDA No. 210044 under 21 U.S.C. § 505(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '139 Patent constitutes infringement of one or more Claims of the '139 Patent under 35 U.S.C. § 271(e)(2).

67. On information and belief, Defendant plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 210044 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

68. On information and belief, the Proposed ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '139 Patent under 35 U.S.C. § 271(a).

69. Upon FDA approval of ANDA No. 210044, Defendant will infringe the '139 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

70. On information and belief, Defendant had knowledge of the '139 Patent when it submitted ANDA No. 210044 to the FDA and Defendant knows or should know that it will aid and abet another's direct infringement of at least one of the Claims of the '139 Patent.

71. The Notice Letter lacks any legal or factual basis for non-infringement of any Claims of the '139 Patent.

72. Defendant has knowledge of the '139 Patent and is knowingly and willfully infringing the '139 Patent.

73. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

74. On information and belief, Defendant lacked a good faith basis for alleging invalidity of the '139 Patent when it filed its Paragraph IV Certification. Accordingly, Defendant's Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,466,139

75. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 74 of this Complaint.

76. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

77. On information and belief, Defendant has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of the '139 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after ANDA No. 210044 is approved.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

a) Judgment that the '122, '160, '680, and '139 Patents are valid and enforceable;

b) Judgment that Defendant's submission of ANDA No. 210044 was an act of infringement of one or more Claims of the '122, '160, '680, and '139 Patents under 35 U.S.C.

§ 271(e)(2);

c) Judgment that Defendant's making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Product prior to the expiration of the '122, '160, '680, and '139 Patents, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more Claims of the '122, '160, '680, and/or '139 Patents;

d) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 210044 shall be a date that is not earlier than the expiration of the '122, '160, '680, and '139 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

e) An Order permanently enjoining Defendant, its affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Defendant, from making, using, offering to sell, selling, marketing, distributing, or importing into the United States the Proposed ANDA Product until after the expiration of the '122, '160, '680, and '139 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

f) Judgment declaring that infringement, inducement or contributory infringement of the '122, '160, '680, and/or '139 Patents by Defendant is willful should Defendant commercially manufacture, use, offer to sell, sell, or import into the United States the Proposed ANDA Product;

g) A declaration that this case is an exceptional case within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

h) Plaintiffs' reasonable costs and expenses in this action; and

i) Such further and other relief as this Court deems proper and just.

Dated: March 24, 2017

Respectfully submitted,

By: s/ John E. Flaherty

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter of the following actions:

- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. SANDOZ INC., and SANDOZ INTERNATIONAL GmbH*, C.A. No. 1:14-cv-03547-RMB-KMW ("*AstraZeneca v. Sandoz*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. SAGENT PHARMACEUTICALS, INC.*, C.A. No. 1:14-cv-05539-RMB-KMW ("*AstraZeneca v. Sagent*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. GLENMARK PHARMACEUTICALS INC., USA*, C.A. No. 1:15-cv-00615-RMB-KMW ("*AstraZeneca v. Glenmark*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. AGILA SPECIALTIES, INC. F/K/A STRIDES INC., ONCO THERAPIES LIMITED, MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC.*, C.A. No. 1:15-cv-06039-RMB-KMW ("*AstraZeneca v. Agila*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC.*, C.A. No. 1:15-cv-07009-RMB-KMW ("*AstraZeneca v. Mylan*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. TEVA PHARMACEUTICALS USA, INC.*, C.A. No. 1:15-cv-07889-RMB-KMW ("*AstraZeneca v. Teva*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. INNOPHARMA, INC.*, C.A. No. 1:16-cv-00894-RMB-KMW ("*AstraZeneca v. InnoPharma Inc.*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. INNOPHARMA LICENSING LLC*, C.A. No. 1:16-cv-01962-RMB-KMW ("*AstraZeneca v. InnoPharma Licensing*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. MYLAN INSTITUTIONAL LLC*, C.A. No. 1:16-cv-04612-RMB-KMW ("*AstraZeneca v. Mylan Institutional*")
- *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.*, C.A. No. 1:17-cv-00926-RMB-KMW ("*AstraZeneca v. Dr. Reddy's*")

The foregoing cases involve AstraZeneca's FASLODEX® (fulvestrant) intramuscular injection product. The FASLODEX® (fulvestrant) intramuscular injection cases have been assigned to Hon. Renée M. Bumb, U.S.D.J. The *AstraZeneca v. Sandoz*, *AstraZeneca v.*

Sagent, and *AstraZeneca v. Glenmark* cases were consolidated by Judge Bumb under lead case, *AstraZeneca Pharms. LP, et al. v. Sandoz Inc., et al.*, Civ. No. 14-cv-03547. The *AstraZeneca v. Agila*, *AstraZeneca v. Mylan*, *AstraZeneca v. Teva*, *AstraZeneca v. Mylan Institutional*, and *AstraZeneca v. InnoPharma Licensing* cases were consolidated by Judge Bumb under Consolidated Case No. 1:15-cv-06039. To date, the following cases have been terminated: *AstraZeneca v. Sandoz*, *AstraZeneca v. Sagent*, *AstraZeneca v. Glenmark*, *AstraZeneca v. InnoPharma Inc.*, *AstraZeneca v. Agila*, *AstraZeneca v. Mylan*, and *AstraZeneca v. Mylan Institutional*. The following cases remain pending before Judge Bumb: *AstraZeneca v. Teva* and *AstraZeneca v. InnoPharma Licensing* (continuing under lead case, *AstraZeneca Pharms. LP, et al. v. Agila Specialties, Inc., et al.*, Civ. No. 15-cv-06039 (Consolidated)) and *AstraZeneca v. Dr. Reddy's* (Civ. No. 1:17-cv-00926). Plaintiffs respectfully request that this case likewise be assigned to Judge Bumb due to her familiarity with the subject matter.

Dated: March 24, 2017

Respectfully submitted,

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